

10-23-06

IFW

Express Mail Label No. _____ Dated: _____

Docket No.: 03818/0204418-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Mladen Mercep et al.

Application No.: 10/595,936

Confirmation No.: 9207

Filed: May 19, 2006

Art Unit: N/A

For: 1,3-DIAZA-DIBENZO[E,H]AZULENES FOR
THE TREATMENT OF CENTRAL
NERVOUS SYSTEM DISEASES AND
DISORDERS

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:
(Check one of the boxes A-D)

- ☐ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above identified national application
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was (check one of boxes (a) or (b))
- ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was

(check one of the boxes "a" and "b" below:)

- ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☒ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

<<INSERT SERIAL NO. & FILING DATE>>

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

- ☒ 3. Cite No(s). _____ are not in the English language.
In accordance with 1.98(c), Applicant states:

- ☒ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
- ☐ The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- ☐ A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ A concise explanation of document(s) _____ can be found on the attached sheet.

- ☐ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).
- ☐ 5. Other information being provided for the examiner's consideration follows:

[A/An International Search Report, dated April 19, 2005, which issued during the prosecution of International Application No. PCT/HR2004/000056 which corresponds to the present application.]

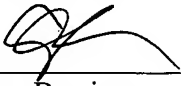
6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: October 20, 2006

Respectfully submitted,

By 

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PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/595,936-Conf. #9207
				Filing Date	May 19, 2006
				First Named Inventor	Mladen Mercep
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	03818/0204418-US0

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA*	US-3,711,489	01-16-1973	Lombardino	
	AB*	US-4,198,421	04-15-1980	Cherkofsky et al.	
	AC*	US-4,145,434	03-20-1979	VAN DER Burg et al.	
	AD*	US-6,511,976	01-28-2003	Andres-Gil et al.	
	AE*	US-3,781,294	12-25-1973	Lombardino	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	WO-96/14320	05-17-1996	Janssen Pharmaceutica N.V.		
	BB	EP-0063525	10-27-1982	Centre National de la Recherche Scientifique		
	BC	CA-967,573	05-13-1975	Pfizer Inc.		
	BD	WO-97/38991	10-23-1997	Janssen Pharmaceutica N.V.		
	BE	WO-99/19317	04-22-1999	Janssen Pharmaceutica N.V.		
	BF	EP-372445	06-13-1990	Du Pont		
	BG	WO-91/18885	12-12-1991	The Du Pont Merck Pharmaceutical Company		
	BH	WO-96/14321	05-17-1996	Janssen Pharmaceutica N.V.		
	BI	WO-03/099823	12-04-2003	Pliva D D et al.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	CA	Saucier, C. et al. "Identification of an Endogenous 5-Hydroxytryptamine 2A Receptor in NIH-3T3 Cells: Agonist-Induced Down-Regulation Involves Decreases in Receptor RNA and Number" <i>Journal of Neurochemistry</i> , 1997 , vol 68:, No. 1, pages 1998 - 2011		
	CB	Thomson W. et al. " Juvenile Idiopathic Arthritis Genetics - What's new? What's next? <i>Arthritis Research</i> , 2002 , vol 4 and 5: pgs 302-306		
	CC	Millan, M.J. et al. "S18126 ({2-4-2,3-dihydrobenzo[1,4] dioxin-6-yl)piperazin-1-ylmethyl}), A Potent, Selective and Competitive Antagonist at Dopamine D4 Receptors: An In vitro and In Vitro and In Vivo Comparison with L 745,870 (3-(4-[4-chlorophenyl]piperazin-1-yl)methyl-1H-pyrrolo[2,3b]pyridine) and Raclopride, 1998 , <i>Journal of Pharmacology and Experimental Therapeutics</i> , vol 287: No. 1 pages 167-186.		
	CD	T.F. Meert, et al. " Psychopharmacology of Ritanserlin: Comparison with Chlordiazepoxide ", <i>Drug Development Research</i> , 1989 , vol. 18, pgs.119-144		
	CE	Niemegeers, C.J.E., et al, "Interaction of Drugs with Apomorphine, Tryptamine and		
Examiner Signature				Date Considered

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/595,936-Conf. #9207
				Filing Date	May 19, 2006
				First Named Inventor	Mladen Mercep
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	03818/0204418-USO

		Norepinephrine. A New 'in vivo' Approach: the ATN-Test in Rats", Arch. Int. Pharmacodyn. Vol. 227, pages 238-253 (1977).	
	CF	Porsolt R.D. et al. " Behavioural Despair in Mice: A Primary Screening Test for Antidepressants" Arch. Int. Pharmacodyn. Vol. 229, pages 327-336 (1977)	
	CG	Wolf,, W.A. et al. "The Serotonin 5-HT 2C Receptor Is a Prominent Serotonin Receptor in Basal Ganglia: Evidence from Functional Studies on Serotonin-Mediated Phosphoinositide Hydrolysis" Journal of Neurochemistry, 1997, vol. 69: pgs. 1449	
	CH	Bonhaus D.W. , et al , " The pharmacology and distribution of human 5-hydroxytryptamine2B (5HT2B) receptor gene products: comparison with 5-HT2A and 5HT2C receptors" British Journal of Pharmacology, (1995), Vol, 115: pages 622-628	
	CI	Berge S. M. et al. "Pharmaceutical Salts," Journal of Pharmaceutical Sciences., 1977; Vol. 66: pages 1-20	
	CJ	Ramamoorthy, S. et al., "Regulation of the Human Serotonin Transporter by Interleukin-1 β " Biochemical and Biophysical Research Communications, 1995, Vol. 216, No. 2, pages 560-567	
	CK	F.Bymaster, et al , " New Approaches to developing antidepressants by enhancing monoaminergic neurotransmission" Expert Opinion Investig. Drugs 2003, 12, 531-543	
	CL	U. Spampinato, et al. " Role of Striatal Serotonin 2A and Serotonin 2C Receptor Subtypes in the Control of In Vivo Dopamine Outflow in the Rat Striatum" J. Neurochemistry 2000, vol. 74, pgs. 693-701	
	CM	F.P. Monnet, et al . "N-Methyl-D-aspartate-induced neuronal activation is selectively modulated by σ receptors" , European Journal of Pharmacology ,1990, vol. 179,, pgs. 441-445.	
	CN	Claghorn, J. et al, "Recent developments in antidepressant agents", Progress in Drug Research Clinic Inc.. 1996, vol.46, pgs.243-262;	
	CO	Sperling, W. et al " New Tetracyclic Antidepressants" Drugs Today , 1997, vol. 33, No. 2, pgs. 95-102.	
	CP	J. Ignacio Andres et al. " R107500.A new 5-HT 2A/2C Antagonist with Potential Anxiolytic Profile" Drugs Fut. 2002, vol. 27, Suppl. A: C41	
	CQ	Jose M. Cid, et al., " Synthesis of 2-aminomethyl-3, 3a, 8, 12, "Drugs Fut. 2002, vol 27, Suppl. A: P182	
	CR	PCT International Search Report for International Application No. April 19, 2005, dated April 19, 2005.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Application No. (if known): 10/595,936

Attorney Docket No.: 03818/0204418-US0

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IDS (Citation) by Applicant (~~07~~References) *& Search rpt*
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